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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,339	02/25/2004	Reynolds G. Gorsuch	TRANSVI.017A	4556

20995 7590 05/17/2007

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EXAMINER	
CRAIG, PAULA L	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
05/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/786,339	GORSUCH ET AL.
	Examiner	**Art Unit**
	Paula L. Craig	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 34-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 34-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to Claims 32 and 34-63 have been considered but are moot in view of the new grounds of rejection. The allowability of former Claims 33-37 and 50-63 indicated in the prior Office Action mailed March 26, 2007 is withdrawn. The finality of the prior Office Action mailed March 26, 2007 is withdrawn.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not disclose the higher mass density zone being characterized by a nominal average pore diameter of between about 0.005 μm and about 0.05 μm, as required by Claim 63.

Claim Objections

3. Claims 39, 40, 42, 52, and 55-60 are objected to because of the following informalities: In Claims 39, 40, and 42, line 1 of each claim, "fiber of" should be "filter device of". Claim 52 fails to further limit the subject matter of Claim 1. In Claims 55 and 58, "a lower" should be "said lower". In Claims 56, 57, 59, and 60, "a higher" should be "said higher". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 32 and 36-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0087109 to Gorsuch et al. in view of Murase (US 2002/0046970).

6. For Claim 32, Gorsuch '109 teaches a filter device for being implanted in a blood vessel for carrying out *in-vivo* plasma separation (Abstract, Figs. 1-2, paragraphs 8-10). The filter device has a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous membrane fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof (elongated hollow tubes are the tubes of triple-lumen catheter 20 and extraction header 16; fibers are hollow fiber membranes 14; Figs. 1-2, paragraphs 8-9 and Claim 1). Gorsuch '109 teaches the fiber wall morphology of each of the elongated fibers being asymmetrical between the inner wall surface and the outer wall surface, with the fiber wall having a higher mass density zone adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone (paragraph 10). Each fiber has a first end and a second end secured to the elongated hollow tubes, wherein the interior of the plurality of elongated hollow tubes communicates with the interior lumen of each of the fibers (elongated

hollow tubes are the tubes of triple-lumen catheter 20 and extraction header 16; fibers are hollow fiber membranes 14; Figs. 1-2, paragraphs 8-10, and Claim 1). Gorsuch '109 does not teach the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an embedded continuous filament to provide a high tensile/rupture strength (filament is reinforcement fiber 3, Abstract, Figs. 3-6, paragraphs 24-25 and 42, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '109 to include an embedded continuous filament, as taught by Murase, for reinforcement of the filter wall to provide a high tensile/rupture strength, as taught by Murase.

7. For Claims 36 and 37, Gorsuch '109 does not teach the filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, or the one or more filaments extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface. Murase teaches a filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, and the one or more filaments extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface (Figs. 3-6 and Claims 1-2). Murase teaches the filament reinforcing the filter (Claim 1). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '109 to include the filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, or the one or more

filaments extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface, as taught by Murase, to provide reinforcement.

8. For Claim 38, Gorsuch '109 does not teach the filament having a substantially uniform tensile strength along its length. However, it is well known in the art for a reinforcing filament to have a substantially uniform tensile strength along its length. It would have been obvious to one of ordinary skill in the art at the time of the invention for the filament to have a substantially uniform tensile strength along its length.

9. For Claims 39-43, Gorsuch '109 does not teach the filament occupying less than about 15%, about 10%, or about 0.01% or about 0.2% to about 2% of the fiber wall cross-sectional area of the fiber. Murase teaches the filament occupying less than 10% or about 0.02% to about 2% of the fiber wall cross-sectional area of the fiber (paragraphs 58, 90, 94, 96, 98, and 100). The percentage of the fiber wall cross-sectional area of the fiber occupied by the filament is a result effective variable, since it affects permeability. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980). Murase teaches that the amount of the fiber wall cross-sectional area occupied by the filament is preferably 10% or less to retain the permeation performance of the filter and avoid resistance to the passage of liquid (paragraphs 58-60). Murase teaches an example of a filament occupying 2% of the cross-sectional area (paragraph 100). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '109 to have the filament occupy less than about 15% or about 10%, or between about 0.01% or 0.2% and about 2% of the fiber wall cross-sectional area of the

fiber, as taught by Murase, to retain the permeation performance of the filter and avoid resistance to the passage of liquid, as taught by Murase.

10. For Claim 44, Gorsuch '109 does not teach the filament having a tensile strength. The tensile strength of the filament is a result effective variable, since it affects the strength of the reinforced fiber. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. Murase teaches the filament having a tensile strength of at least about 5,000 psi, so that the filament can have a tensile strength significantly higher than the surrounding part of the fiber (paragraphs 56-57). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '109 to include the filament having a tensile strength of at least about 5,000 psi, as taught by Murase.

11. For Claim 45, Gorsuch '109 does not teach a filament. Murase teaches the filament being made of a variety of materials (paragraph 46). Murase teaches the filament including fiberglass, polypropylene, or polyamide (paragraphs 46-52). It would have been obvious to one of ordinary skill in the art to manufacture the filament from a suitable material, as taught by Murase.

12. For Claim 46, Gorsuch '109 does not teach a filament. Murase teaches the fiber having two filaments (paragraphs 93 and 97). Murase teaches that the number of filaments can be changed in accordance with the physical properties required (paragraph 85). It would have been obvious to one of ordinary skill in the art to have an appropriate number of filaments, as taught by Murase, to provide the physical properties required, as taught by Murase.

13. For Claim 47, Gorsuch '109 does not teach a filament. Murase teaches the filament including fiberglass, polypropylene, or polyamide (paragraphs 46-52).

14. For Claims 48 and 49, Gorsuch '109 does not teach a filament. Murase teaches each of the filaments having a cross-sectional area occupying between about 0.2% and about 2% or about 0.5% and about 5% of the cross-sectional area of the fiber, as described above for Claims 39-43 in paragraph 8. It would have been obvious to one of ordinary skill in the art to modify Gorsuch '109 to include each of the filaments having a cross-sectional area occupying between about 0.2% and about 2% of the cross-sectional area of the fiber, for the same reasons as described above for Claims 39-43 in paragraph 8.

15. For Claim 50, Gorsuch '109 teaches a continuous change in mass density from the outer wall surface to the inner wall surface (paragraphs 2 and 10; note that U.S. Patent Application No. 09/549,131, which issued as U.S. Patent No. 6,802,820 to Gorsuch et al., is incorporated by reference).

16. For Claim 51, Gorsuch '109 teaches the fiber wall structure including a continuum of voids bounded by solid frames (paragraphs 2 and 10; note that U.S. Patent Application No. 09/549,131, issued as U.S. Patent No. 6,802,820 to Gorsuch et al., is incorporated by reference).

17. For Claims 52-54, Gorsuch '109 teaches the membrane fiber wall having two, three, or four or more mass density zones and each of the zones being characterized by a different average nominal pore size (paragraphs 2 and 10; note that U.S. Patent

Application No. 09/549,131, issued as U.S. Patent No. 6,802,820 to Gorsuch et al., is incorporated by reference).

18. For Claims 55-63, Gorsuch '109 teaches the filter device having: a lower mass density zone characterized by a nominal average pore diameter of between about 1 μm and about 60 μm, or about 2 μm and about 6 μm; or a higher mass density zone characterized by a nominal average pore diameter of between about 0.3 μm and about 1 μm, or about 0.4 μm and about 0.8 μm, or about 0.005 μm and about 0.05 μm; or one or more intermediate mass density zones having a nominal average pore diameter of between about 0.8 μm and about 2 μm; or two intermediate mass density zones, a first intermediate zone having a nominal average pore diameter of between about 0.8 μm and about 1.2 μm and a second intermediate zone having a nominal average pore diameter of between about 1.2 μm and about 2 μm (paragraphs 2 and 10; note that U.S. Patent Application No. 09/549,131, issued as U.S. Patent No. 6,802,820 to Gorsuch et al., is incorporated by reference).

19. Claims 32 and 36-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0236482 to Gorsuch et al. in view of Murase.

20. For Claim 32, Gorsuch '482 teaches a filter device for being implanted in a blood vessel for carrying out *in-vivo* plasma separation (Abstract, Figs. 1-2, paragraphs 9-11). The filter device has a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous membrane fiber wall with an outer wall surface

and an inner wall surface defining an interior lumen extending along the length thereof (elongated hollow tubes are the tubes of triple-lumen catheter 20 and extraction header 16; fibers are hollow fiber membranes 14; Figs. 1-2, paragraphs 9-11 and Claim 1). Gorsuch '482 teaches the fiber wall morphology of each of the elongated fibers being asymmetrical between the inner wall surface and the outer wall surface, with the fiber wall having a higher mass density zone adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone (paragraph 11). Each fiber has a first end and a second end secured to the elongated hollow tubes, wherein the interior of the plurality of elongated hollow tubes communicates with the interior lumen of each of the fibers (elongated hollow tubes are the tubes of triple-lumen catheter 20 and extraction header 16; fibers are hollow fiber membranes 14; Figs. 1-2, paragraphs 9-11, and Claim 1). Gorsuch '482 does not teach the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an embedded continuous filament to provide a high tensile/rupture strength (filament is reinforcement fiber 3, Abstract, Figs. 3-6, paragraphs 24-25 and 42, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '482 to include an embedded continuous filament, as taught by Murase, for reinforcement of the filter wall to provide a high tensile/rupture strength, as taught by Murase.

21. Claims 36-63 are rejected over Gorsuch '482 over Murase for reasons similar to those described above for Gorsuch '109 over Murase in paragraphs 7-17 (note that Gorsuch '482 is a continuation-in-part of Gorsuch '109; paragraph 3 of Gorsuch '482 also incorporates by reference U.S. Patent Application No. 09/549,131, which issued as U.S. Patent No. 6,802,820).

22. Claims 32 and 34-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0034317 to Gorsuch et al. in view of Murase.

23. For Claim 32, Gorsuch '317 teaches a filter device for being implanted in a blood vessel for carrying out *in-vivo* plasma separation (Abstract, Figs. 1-7, paragraphs 9-11). The filter device has a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous membrane fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof (elongated hollow tubes are the tubes of triple-lumen catheter 20 and header 14, including tubes 16 and 18; fibers are microporous fibers 12; Figs. 1-6, paragraphs 3-4, 12-13, and 20, and Claims 13-14). Gorsuch '317 teaches the fiber wall morphology of each of the elongated fibers being asymmetrical between the inner wall surface and the outer wall surface, with the fiber wall having a higher mass density zone adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone (Fig. 7 and paragraph 24). Each fiber

has a first end and a second end secured to the elongated hollow tubes, wherein the interior of the plurality of elongated hollow tubes communicates with the interior lumen of each of the fibers (elongated hollow tubes are the tubes of triple-lumen catheter 20 and header 14, including tubes 16 and 18; fibers are microporous fibers 12; Figs. 1-6, paragraphs 12 and 20-22, and Claim 13). Gorsuch '317 does not teach the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an embedded continuous filament to provide a high tensile/rupture strength (filament is reinforcement fiber 3, Abstract, Figs. 3-6, paragraphs 24-25 and 42, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '317 to include an embedded continuous filament, as taught by Murase, for reinforcement of the filter wall to provide a high tensile/rupture strength, as taught by Murase.

24. For Claim 34, Gorsuch '317 teaches the plurality of elongated hollow tubes including one or more first and one or more second elongated hollow tubes extending substantially parallel along the length thereof, and a first end of each of the elongated microporous fibers being secured to the first hollow tube and a second end of each of the fibers being secured to the second hollow tube whereby the interior fiber lumen of each fiber communicates with the interior of the first and the second hollow tube (Figs. 1 and 4-5 and paragraphs 12, 20, and 22).

25. For Claim 35, Gorsuch '317 teaches two of the elongated hollow tubes, each of the tubes having a plurality of holes spaced apart along a substantial portion of the

length thereof, each hole receiving a first or a second end of an elongated microporous fiber (Figs. 1 and 4-5 and paragraphs 12, 20, and 22).

26. Claims 36-63 are rejected over Gorsuch '317 over Murase for reasons similar to those described above for Gorsuch '109 over Murase in paragraphs 7-17 (note paragraph 24 of Gorsuch '317 incorporates by reference U.S. Patent Application No. 09/549,131, which issued as U.S. Patent No. 6,802,820).

27. Claims 32 and 36-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,802,820 to Gorsuch et al. in view of Murase.

28. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

29. For Claim 32, Gorsuch '820 teaches a filter device for being implanted in a blood vessel for carrying out *in-vivo* plasma separation (Abstract, Figs. 1-6, col. 1, lines 6-24, col. 1, line 66 to col. 2, line 24, and Claims 1-2; note U.S. Patent Nos. 4,950,224, 5152,743, and 5,735,809 are incorporated by reference). The filter device has a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous membrane fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof (Figs. 1-6, col. 1, lines 6-24, col. 1, line 66 to col. 2, line 67, and Claims 1-2; note U.S. Patent Nos. 4,950,224, 5,152,743, and 5,735,809 are incorporated by reference). Gorsuch '820 teaches the fiber wall morphology of each of the elongated fibers being asymmetrical between the inner wall surface and the outer wall surface, with the fiber wall having a higher mass density zone adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone (Figs. 1-6, col. 2, line 50 to col. 3, line 56). Each fiber has a first end and a second end secured to the elongated hollow tubes, wherein the interior of the plurality of elongated hollow tubes communicates with the interior lumen of each of the fibers (col. 1, lines 6-24, col. 1, line 66 to col. 2, line 24; note U.S. Patent No. 5,735,809 is incorporated by reference). Gorsuch '820 does not teach the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a

continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an embedded continuous filament to provide a high tensile/rupture strength (filament is reinforcement fiber 3, Abstract, Figs. 3-6, paragraphs 24-25 and 42, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '820 to include an embedded continuous filament, as taught by Murase, for reinforcement of the filter wall to provide a high tensile/rupture strength, as taught by Murase.

30. For Claims 36 and 37, Gorsuch '820 does not teach the filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, or the one or more filaments extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface. Murase teaches a filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, and the one or more filaments extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface (Figs. 3-6 and Claims 1-2). Murase teaches the filament reinforcing the filter (Claim 1). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '820 to include the filament extending along the fiber wall substantially uniformly between the inner wall surface and the outer wall surface, or the one or more filaments extending along the fiber wall substantially equidistant between the inner wall surface and the outer wall surface, as taught by Murase, to provide reinforcement.

31. For Claim 38, Gorsuch '820 does not teach the filament having a substantially uniform tensile strength along its length. However, it is well known in the art for a

reinforcing filament to have a substantially uniform tensile strength along its length. It would have been obvious to one of ordinary skill in the art at the time of the invention for the filament to have a substantially uniform tensile strength along its length.

32. For Claims 39-43, Gorsuch '820 does not teach the filament occupying less than about 15%, about 10%, or about 0.01% or about 0.2% to about 2% of the fiber wall cross-sectional area of the fiber. Murase teaches the filament occupying less than 10% or about 0.02% to about 2% of the fiber wall cross-sectional area of the fiber (paragraphs 58, 90, 94, 96, 98, and 100). The percentage of the fiber wall cross-sectional area of the fiber occupied by the filament is a result effective variable, since it affects permeability. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney,* 205 USPQ 215 (CCPA 1980). Murase teaches that the amount of the fiber wall cross-sectional area occupied by the filament is preferably 10% or less to retain the permeation performance of the filter and avoid resistance to the passage of liquid (paragraphs 58-60). Murase teaches an example of a filament occupying 2% of the cross-sectional area (paragraph 100). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '820 to have the filament occupy less than about 15% or about 10%, or between about 0.01% or 0.2% and about 2% of the fiber wall cross-sectional area of the fiber, as taught by Murase, to retain the permeation performance of the filter and avoid resistance to the passage of liquid, as taught by Murase.

33. For Claim 44, Gorsuch '820 does not teach the filament having a tensile strength. The tensile strength of the filament is a result effective variable, since it affects the

strength of the reinforced fiber. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. Murase teaches the filament having a tensile strength of at least about 5,000 psi, so that the filament can have a tensile strength significantly higher than the surrounding part of the fiber (paragraphs 56-57). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '820 to include the filament having a tensile strength of at least about 5,000 psi, as taught by Murase.

34. For Claim 45, Gorsuch '820 does not teach a filament. Murase teaches the filament being made of a variety of materials (paragraph 46). Murase teaches the filament including fiberglass, polypropylene, or polyamide (paragraphs 46-52). It would have been obvious to one of ordinary skill in the art to manufacture the filament from a suitable material, as taught by Murase.

35. For Claim 46, Gorsuch '820 does not teach a filament. Murase teaches the fiber having two filaments (paragraphs 93 and 97). Murase teaches that the number of filaments can be changed in accordance with the physical properties required (paragraph 85). It would have been obvious to one of ordinary skill in the art to have an appropriate number of filaments, as taught by Murase, to provide the physical properties required, as taught by Murase.

36. For Claim 47, Gorsuch '820 does not teach a filament. Murase teaches the filament including fiberglass, polypropylene, or polyamide (paragraphs 46-52).

37. For Claims 48 and 49, Gorsuch '820 does not teach a filament. Murase teaches each of the filaments having a cross-sectional area occupying between about 0.2% and

about 2% or about 0.5% and about 5% of the cross-sectional area of the fiber, as described above for Claims 39-43 in paragraph 30. It would have been obvious to one of ordinary skill in the art to modify Gorsuch '820 to include each of the filaments having a cross-sectional area occupying between about 0.2% and about 2% of the cross-sectional area of the fiber, for the same reasons as described above for Claims 39-43 in paragraph 30.

38. For Claim 50, Gorsuch '820 teaches a continuous change in mass density from the outer wall surface to the inner wall surface (Figs. 1-6, col. 2, lines 50-67).

39. For Claim 51, Gorsuch '820 teaches the fiber wall structure including a continuum of voids bounded by solid frames (Figs. 1-6, col. 2, lines 50-67).

40. For Claims 52-54, Gorsuch '820 teaches the membrane fiber wall having two, three, or four or more mass density zones and each of the zones being characterized by a different average nominal pore size (Figs. 1-6, col. 2, line 50 to col. 3, line 56).

41. For Claims 55-63, Gorsuch '820 teaches the filter device having: a lower mass density zone characterized by a nominal average pore diameter of between about 1 μm and about 60 μm, or about 2 μm and about 6 μm; or a higher mass density zone characterized by a nominal average pore diameter of between about 0.3 μm and about 1 μm, or about 0.4 μm and about 0.8 μm, or about 0.005 μm and about 0.05 μm; or one or more intermediate mass density zones having a nominal average pore diameter of between about 0.8 μm and about 2 μm; or two intermediate mass density zones, a first intermediate zone having a nominal average pore diameter of between about 0.8 μm and about 1.2 μm and a second intermediate zone having a nominal average pore

diameter of between about 1.2 μm and about 2 μm (Figs. 1-6, col. 2, line 50 to col. 3, line 56, Claims 7-11, 13, 17, 19, and 21-24).

Double Patenting

42. Claim 32 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1, 12, and 18 of U.S. Patent No. 6,659,973 to Gorsuch in view of Murase. Gorsuch '973 claims a filter device for being implanted in a blood vessel for carrying out *in-vivo* plasma separation, the filter device having a plurality of elongated hollow tubes and a plurality of elongated fibers, each fiber having a microporous membrane fiber wall with an outer wall surface and an inner wall surface defining an interior lumen extending along the length thereof (Claims 1 and 12). Gorsuch '973 claims the fiber wall morphology of each of the elongated fibers being asymmetrical between the inner wall surface and the outer wall surface, with the fiber wall having a higher mass density zone adjacent to the outer wall surface and a lower mass density zone adjacent to the inner wall surface, the higher mass density zone having a smaller average nominal pore size than the average nominal pore size in the lower mass density zone (Claim 18). Each fiber has a first end and a second end secured to the elongated hollow tubes, wherein the interior of the plurality of elongated hollow tubes communicates with the interior lumen of each of the fibers (Claims 1 and 12). Gorsuch '973 does not claim the fibers including a continuous filament embedded in the microporous fiber wall. However, reinforcement of a filter wall with a continuous filament is well known in the art. Murase confirms this and teaches a filter wall with an

embedded continuous filament to provide a high tensile/rupture strength (filament is reinforcement fiber 3, Abstract, Figs. 3-6, paragraphs 24-25 and 42, and Claims 1-2). It would have been obvious to one of ordinary skill in the art to modify Gorsuch '973 to include an embedded continuous filament, as taught by Murase, for reinforcement of the filter wall to provide a high tensile/rupture strength, as taught by Murase.

43. Claim 32 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 12 of U.S. Patent No. 6,849,183 to Gorsuch in view of Murase, for reasons similar to those described above for Gorsuch '973 over Murase in paragraph 40.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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